Memo of Meeting

Date: June 14, 2001

Location: 1350 Piccard Drive
Rockville, MD

Subject: ProPackData Electronic Recordkeeping System

Representing ProPackData Corporation, Cary North Carolina:

Mr. Hermann Schaefer, Director Customer Services,

Mr. Christian Fortunel, President

Dr. Gerhard Werling, Director, Quality Management & Validation Services

Representing the Food and Drug Administration,

Dr. Charles Snipes, Compliance Officer, Center For Drug Evaluation and Research

Mr. Paul J. Motise, Consumer Safety Officer, Office of Enforcement

Mr. Scott MacIntire, Director, Division of Compliance Information and Quality Assurance, Office of Enforcement

Dr. James McCormack, Consumer Safety Officer, Office of Enforcement

Mr. Tom Chin, Consumer Safety Officer, Office of Enforcement

Mr. Thomas Santucci, Computer Specialist, Office of Enforcement

The meeting was requested by Propack Data to discuss the firm's electronic recordkeeping software in the context of 21 CFR Part 11.

At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products and services that enable people to meet FDA regulations, and that our comments should not be taken as FDA review, approval or disapproval of the Propack Data products.

The firm's representatives explained that their software, the PMX system, has part 11 functionality and they wanted our input as to their interpretation of the

regulations. The representatives gave us a brief presentation, following the attached PowerPoint slides.

Acrobat Document

The representatives explained that ProPack Data is based in Germany, with branches in the U.S., France, Italy, and the U.K. About 85% of the firm's customers are pharmaceutical producers, many based in the U.S.; the firm also has customers in the food and biotechnology industries. The firm's core product, PMX integrates activities in product research, production, and quality control. The representatives gave us a broad overview of the product architecture, key modules, and how it interacts with other applications such as Oracle and SAP. PMX operates on Windows NT, Unix and Oracle platforms.

During the meeting we discussed the firm's approach to software validation. The representatives explained their two step approach that includes pre-validation of a standard package and validation of the customer's system. Program modules are included in the customer's system per the customer's requirements; functionality is mapped to program modules, dependencies among modules are taken into consideration, and test plans are developed. Validation documentation and customer test scripts are developed, including interfaces to customers' other systems. Design qualification documentation is held under third party escrow, although documentation of installation, operation and performance qualification is provided. The firm accepts customer audits and participates in the PDA software vendor qualification program (Technical Report 32.)

We reviewed several part 11 technical requirements and how the firm intended to have its software meet them. These include authority checks, audit trails, sequencing checks, archiving, electronic copies of electronic records, electronic signature manifestation, electronic signature components and controls for identification codes used together with passwords.

With respect to electronic copies of electronic records, the system generates Adobe PDF files. We commented that to be suitable for our use electronic copies need to be in a format that permits us to process (e.g., search and sort) information. Thus, a PDF file of a table or spreadsheet would not meet this need, although a word searchable text file may meet this requirement.

Electronic records are archived in electronic form; PDF is used for long term storage. We commented that, here too, archived records need to be in a form that permits content to be processed and electronic signatures to be verified. The representatives commented that to their knowledge none of their customers

has, in fact, exercised the software option that compresses the archive to an unprocessable form.

Regarding access restrictions, the representatives explained that the software provides for configurable access according to user profiles.

Concerning password security, the system requires a password length of at least six characters, at least one of which must be a number or a special character. The program also allows system managers to restrict password reuse and configure password expiration periods. In addition, the program is structured such that system administrators do not know user passwords.

System lockouts during periods of end user inactivity can be configured and failed log in attempts are recorded. However, the system does not report in an urgent manner, attempts at system compromise; instead, security personnel must review a log to determine potential threats. If logs are not reviewed frequently enough, a security breech could go undetected for a period of time. The representatives explained that in future revisions of the program they will include a feature to send an e-mail message to designated security personnel when such events occur.

Regarding audit trails, the program provides for time stamped automatic recording of operator actions that create, delete or modify an electronic record. Altered information is preserved in separate fields. The audit trail identifies operators by their log in names. A field provides for recording the reason for a change. We commented that part 11 does not require the audit trail to record the reason why a record was changed, although a predicate regulation may require recording that information in the trailed record itself. The representatives explained that prior to software delivery, end users may specify that the audit trail be deactivated for certain fields; de-activation would be “hard coded” and thus end users could not reactivate the audit trail. We objected to this practice, and explained that it would be too easy for a customer to inadvertently turn off audit trailing for a field that, per FDA requirements, must be audit trailed. The representatives said that the list of non-audit trailed fields would be included in the end user’s functional list. Electronic copies of audit trails are exportable in PDF format; we commented that, as explained above, this may not be acceptable if information in the audit trail could not be processed.

We discussed changes to electronic records and suggested that an auditor should not have to comb through a separate audit trail to determine if and how an electronic record was altered. We commented that there should be some flag or indication of change in the trailed record itself.

The program allows managers to configure and enforce event sequencing, so that, for example, elements in a pharmaceutical batch production record are completed in the proscribed order.

Manifestations of electronic signatures include the signer's printed name, date and time of signing and the meaning of the signature. The meaning is either explicitly stated or inferred from the record's content.

Electronic signature to record linkage is attained through the database structure.

The meeting concluded after about two hours.

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P. Motise 07/11/01

cc: HFA-224
HFC-200
FDA Meeting Attendees
Part 11 Guidance Dockets

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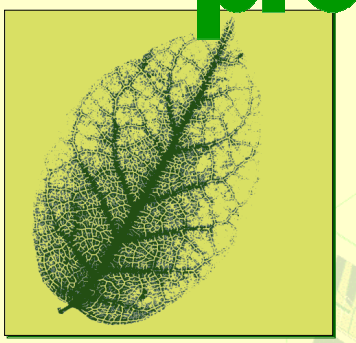

Meeting
Food and Drug Administration

Rockville
June 14, 2001

One-Source Supplier for
Enterprise Production Management

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Propack Data Corporation • 2000 Regency Parkway, Suite 375 • Cary, NC 27511 • USA • www.propack-data.com

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PD - PRESENTATION TEAM

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AGENDA

- INTRODUCTION
- COMPANY OVERVIEW
- PMX ARCHITECTURE
- VALIDATION APPROACH
- IMPLEMENTATION OF 21 CFR PART 11
- DISCUSSION

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OBJECTIVE

- Provide insight into PMX system functionality with special focus on implementation of 21 CFR Part 11
- Get feedback of Propack Data‘s interpretation of 21 CFR Part 11

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GLOBAL ACTION - LOCAL REACH

Propack Data Corporation
American Headquarters
Cary, NC, USA

Branch Offices in
Parsippany, NJ
Chicago, IL (planned)

Propack Data S.r.L.
Vimercate (MI), Italy

Propack Data Ltd.
Stansted/ London, UK

Propack Data S.A.S.
Toulouse, France

Propack Data GmbH
Global Headquarters
Karlsruhe, Germany

Branch Offices in
Bad Säckingen, Bad Wurzach,
Bergisch Gladbach, Leipzig

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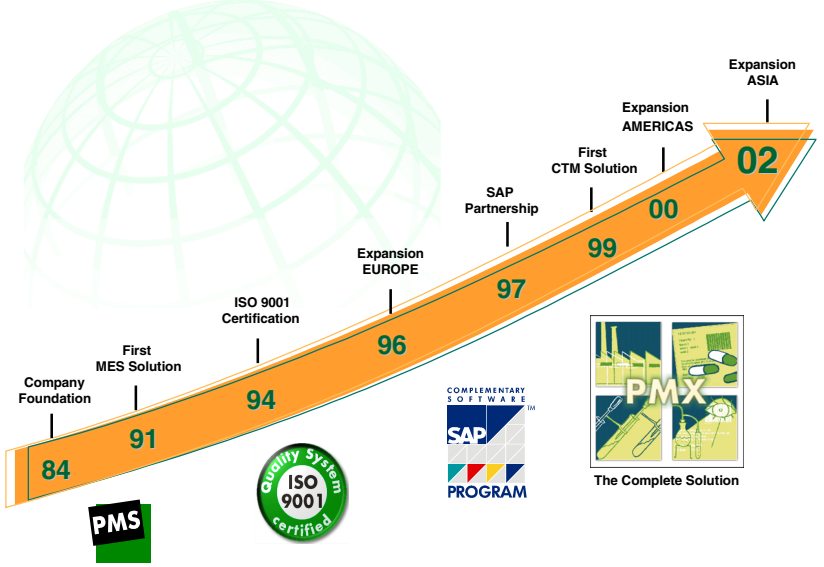
HISTORY & OUTLOOK

Products & Markets



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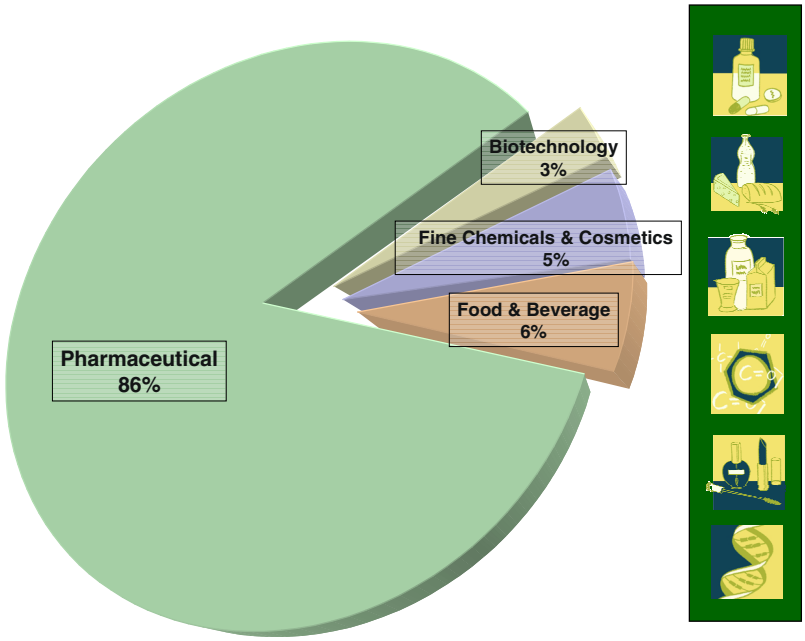
STRONG FOCUS ON PHARMA



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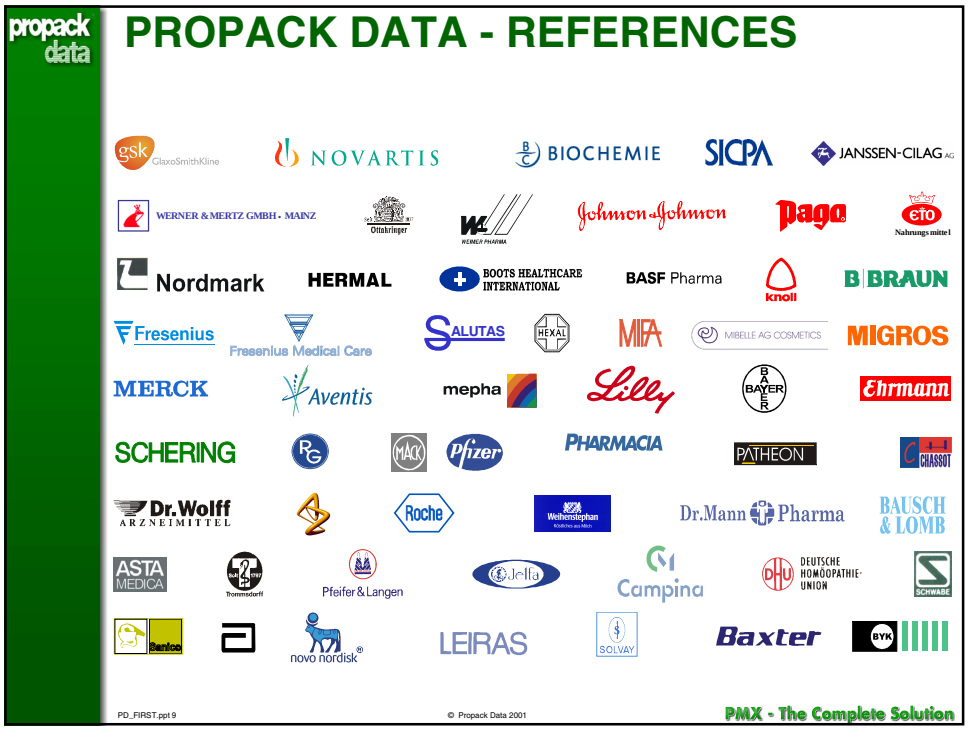
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PROPACK DATA - REFERENCES
GlaxoSmithKline
NOVARTIS
BIOCHEMIE
SICPA
JANSSEN-CILAG
WERNER & MERTZ GMBH · MAINZ
Johnson & Johnson
Pago
Nordmark
HERMAL
BOOTS HEALTHCARE INTERNATIONAL
BASF Pharma
knoll
B BRAUN
Fresenius
Fresenius Medical Care
SALUTAS
HEXAL
MIFA
MIBELLE AG COSMETICS
MIGROS
MERCK
Aventis
mepha
Lilly
BAYER
Ehrmann
SCHERING
Pfizer
PHARMACIA
PATHEON
CHASSOT
Dr. Wolff ARZNEIMITTEL
Roche
Dr. Mann Pharma
BAUSCH & LOMB
ASTA MEDICA
Pfeifer & Langen
Jella
Campina
DEUTSCHE HOMÖOPATHIE-UNION
SCHWABE
Servier
novo nordisk
LEIRAS
SOLVAY
Baxter
BYK
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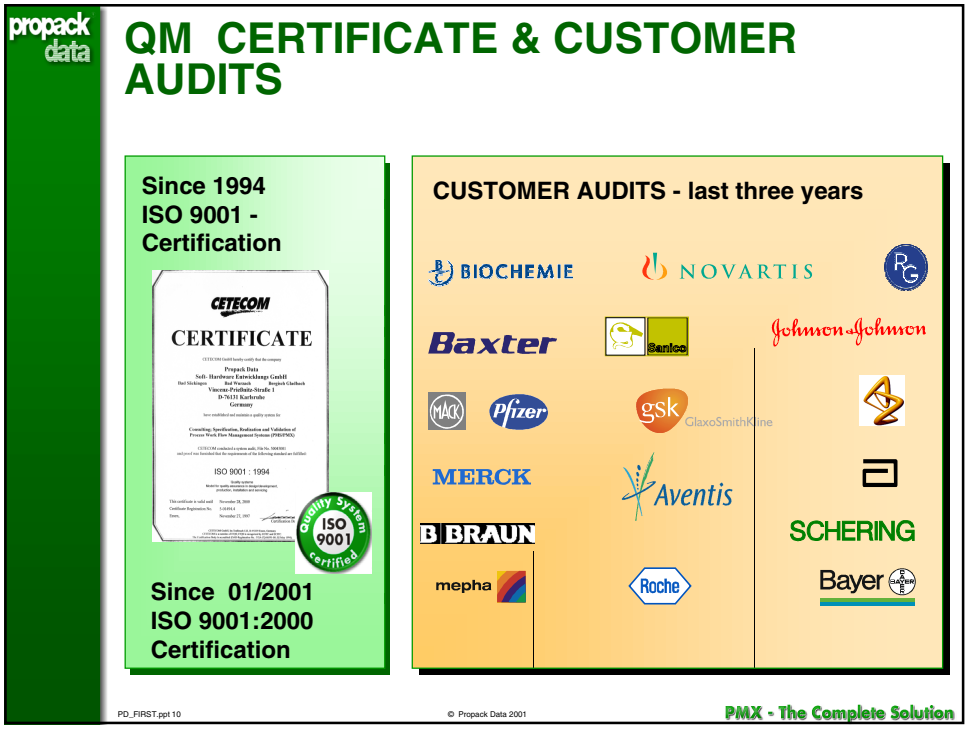
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QM CERTIFICATE & CUSTOMER AUDITS
Since 1994
ISO 9001 -
Certification
CETECOM
CERTIFICATE
ISO 9001 : 1994
Quality System ISO 9001 certified
Since 01/2001
ISO 9001:2000
Certification
CUSTOMER AUDITS - last three years
BIOCHEMIE
NOVARTIS
Baxter
Servier
Johnson & Johnson
Pfizer
gsk GlaxoSmithKline
MERCK
Aventis
B BRAUN
SCHERING
mepha
Roche
Bayer
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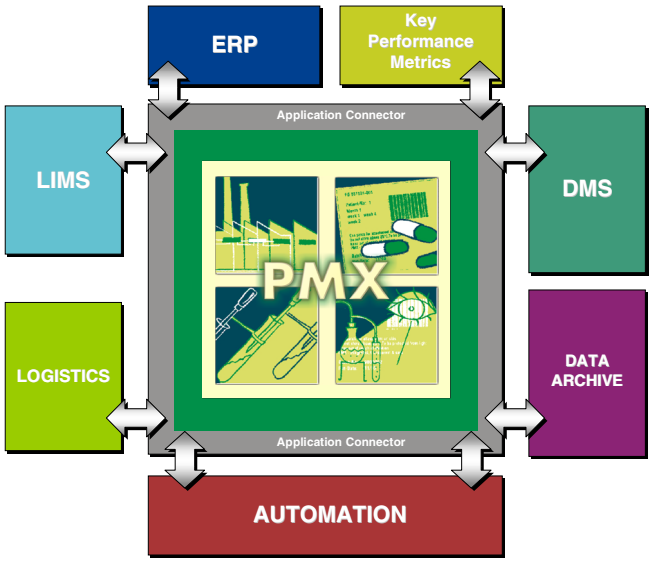
INTEGRATED SOLUTION



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PMX THE COMPLETE SOLUTION

RDM
Utmost Flexibility
Research & Development Management

MES
Paramount Efficiency and Quality
Manufacturing Execution System

CTM
Complete Control and Overview
Clinical Trial Management

MQS
Total Quality Management
Manufacturing Quality Service

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PMX IMPROVES cGMP COMPLIANCE

"Improve cGMP compliance"

Material Reconciliation	DISY
Weigh / Dispense	
Authorization Control	EBR
Batch Record	
Audit Trail	EDB
Controls for identification	EINLOP
Recipe Management	
Sequencing of Work Flow	LIMOS
Device checks	
Material Identification	PALETTI
Lot Management	
Archiving	PDB
Reporting	
Staff Qualification	PEPS
Maintenance	TEDIS

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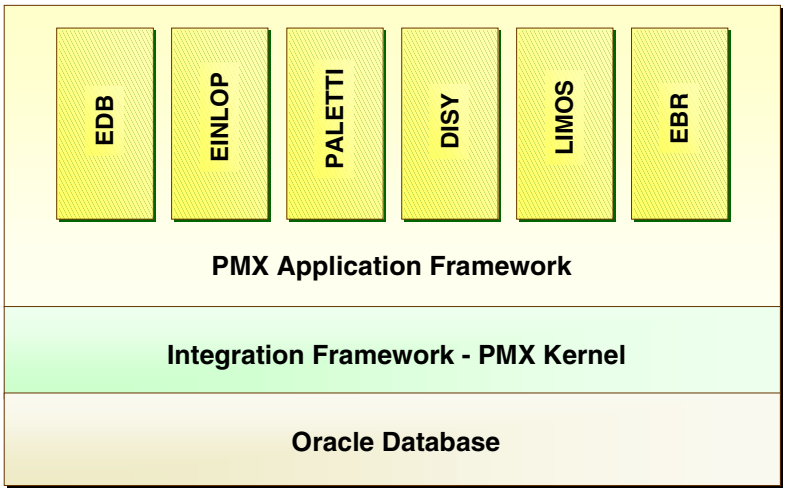
PMX ARCHITECTURE



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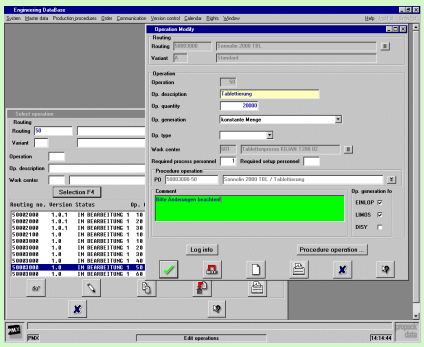
PRODUCTION KNOWLEDGE MANAGEMENT

E D B

- Master data management
  - work centers
  - BOM items
  - storage
  - company and shift calendars
  - users
- Version-controlled master data
  - Master recipe procedures
  - bills of material
  - Master recipes
  - SOPs
  - Master recipe operations
- Electronic signatures
- Editor (Word-compatible)



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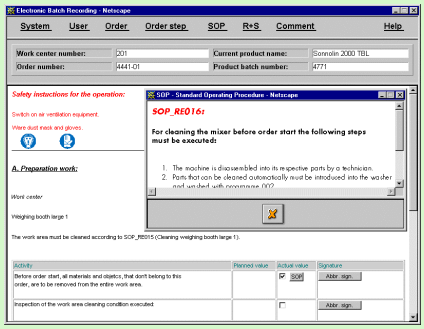
ELECTRONIC BATCH RECORDING

E B R

- Interactive HTML-based on-line process control
- Operator-related electronic signature
- Electronic link to batch processing technology via PLC, scales, process equipment
- Automated generation of the production protocol



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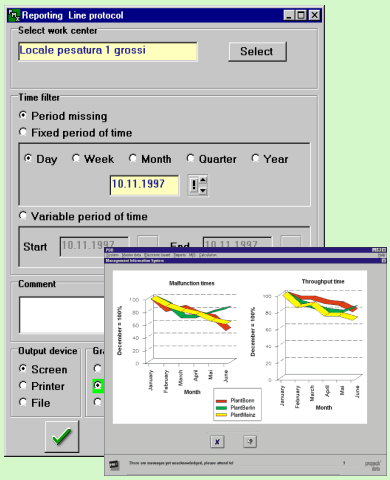
PRODUCTION DATA AND BATCH ARCHIVE

P D B

- SQL-based reporting functions
- Long-term batch archive
- External archive management
- Document scanning



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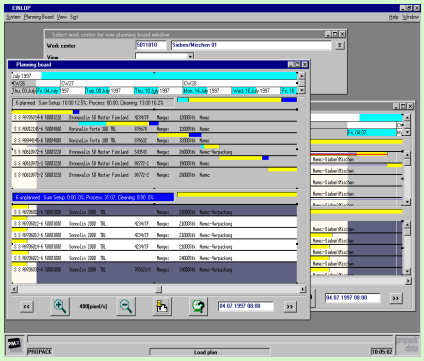
PRODUCTION SCHEDULING & CONTROL

E I N L O P

- Electronic planning board
- Interface to ERP
- Optimal order sequencing
- Optimization of set-up times
- Resource requirements
- Personnel placement plan
- Checking of dates and resources
- Simulations
- Monitoring of order progress



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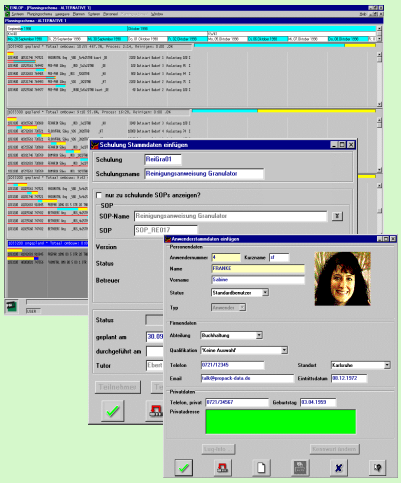
QUALIFICATION MANAGEMENT

P E P S

- Personnel qualification data
- Staff qualification, training administration
- Plant- / GxP- and SOP-related instructions
- Order-related placement planning
- GxP Training Management
- Trigger based deviation reporting
- Reports



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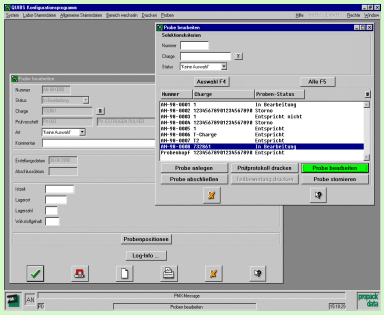
QUALITY MANAGEMENT

QUIBS

- GLP/FDA-compliant master data management (check plans, check items, processes, etc.)
- Process-attending in-process control during production and packaging at the work center/laboratory
- Sampling at goods receipt/issue as well as during process
- Order processing in analytic, microbiology and stability laboratories (chemical/physical and microbiological analysis procedures)
- Batch control and evaluation on the basis of research results
- Quality certificates/Certificates of analysis
- Documentation, reports
- Automatic download of check results



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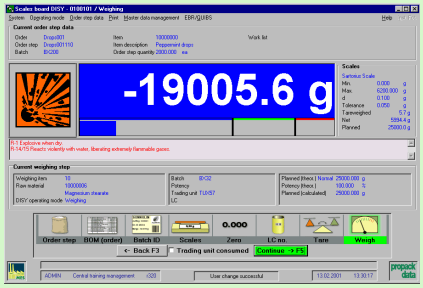
DISPENSING AND WEIGHING SYSTEM

D I S Y

- Identification of containers and input materials with RF-scanners
- Recipe-based weighing
- Open scales interfaces, automation of dosage device
- Labeling, weighing protocol, batch documentation
- Integration with EBR



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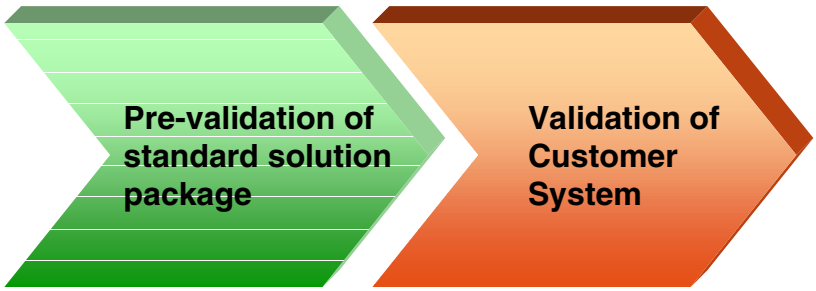
VALIDATION STRATEGY

A TWO-STEP APPROACH



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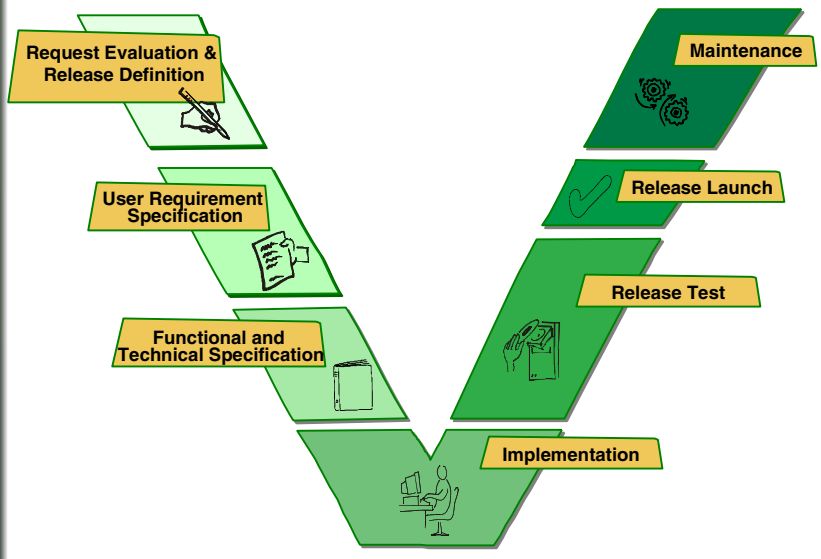
PRE-VALIDATION OF STANDARD PACKAGE



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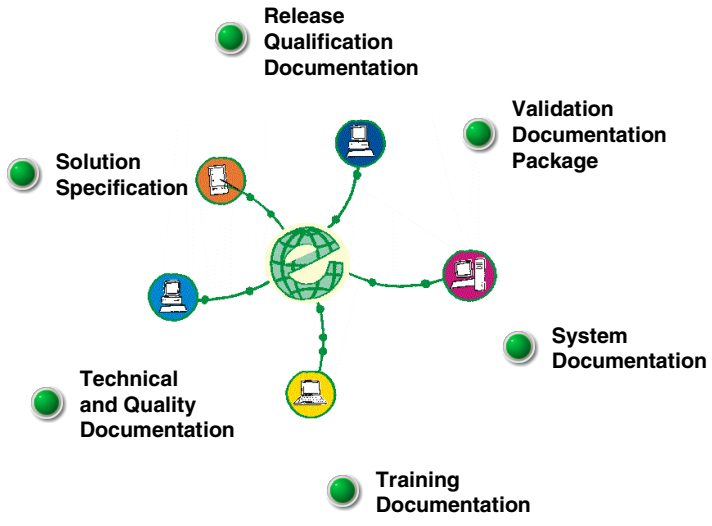
RELEASE DOCUMENTATION



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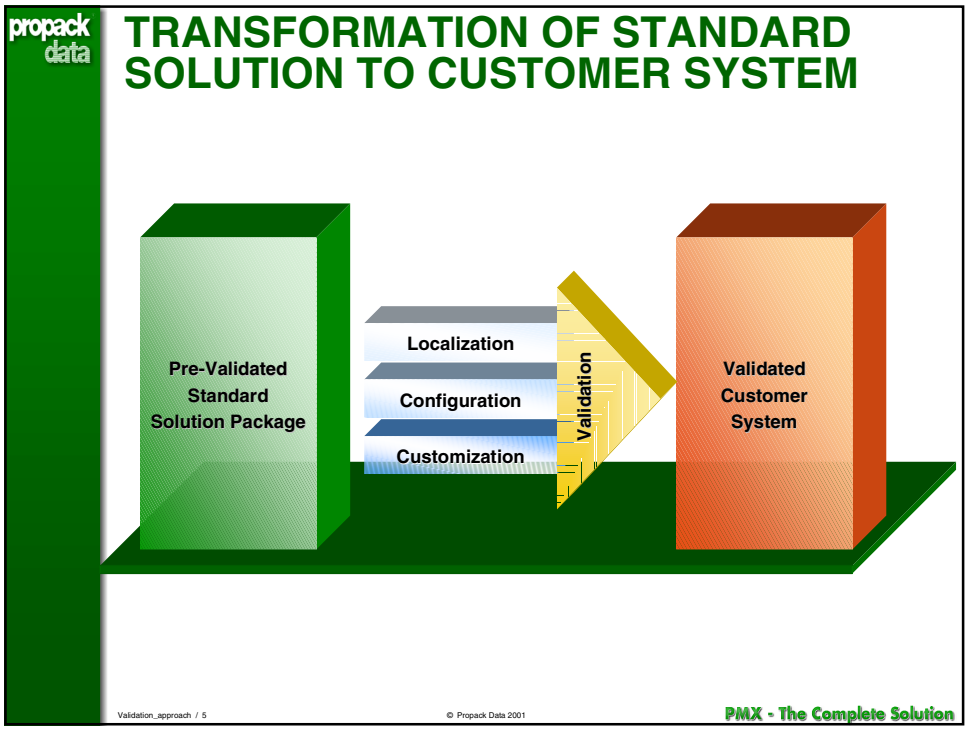
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TRANSFORMATION OF STANDARD SOLUTION TO CUSTOMER SYSTEM
Pre-Validated Standard Solution Package
Localization
Configuration
Customization
Validation
Validated Customer System
Validation_approach / 5
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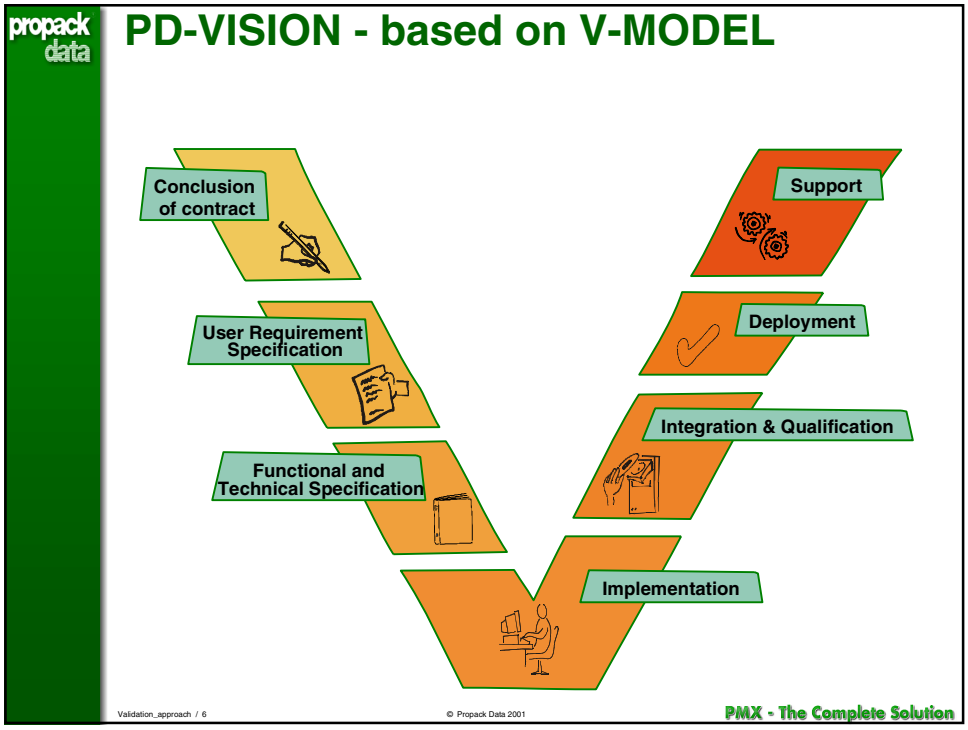
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PD-VISION - based on V-MODEL
Conclusion of contract
User Requirement Specification
Functional and Technical Specification
Implementation
Integration & Qualification
Deployment
Support
Validation_approach / 6
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TEST STRATEGY

- Test suite with phase specific test objective and low redundancy between phases
- Maximum ”re-usability” of testing
- Focus on changes applied to standard software
- Test specification based on documented risk analysis to access impact of changes

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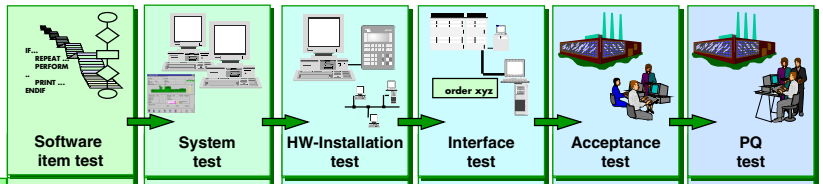
TEST METHOD



	Software item test	System test	HW-Installation test	Interface test	Acceptance test	PQ test
test object	Software-Element	Function / Transaction	Hardware	Interfaces to other systems	Business processes	complete system in operational environment
test strategy	white box test	black box test; Challenge Tests completeness	check of functionality and Tests	black box test; Challenge process level	Challenge testing on	test in operational environment
Focus	Code for Change or Enhancement	New or customized Functions		New or customized interfaces	GxP - relevant processes	GxP - relevant data

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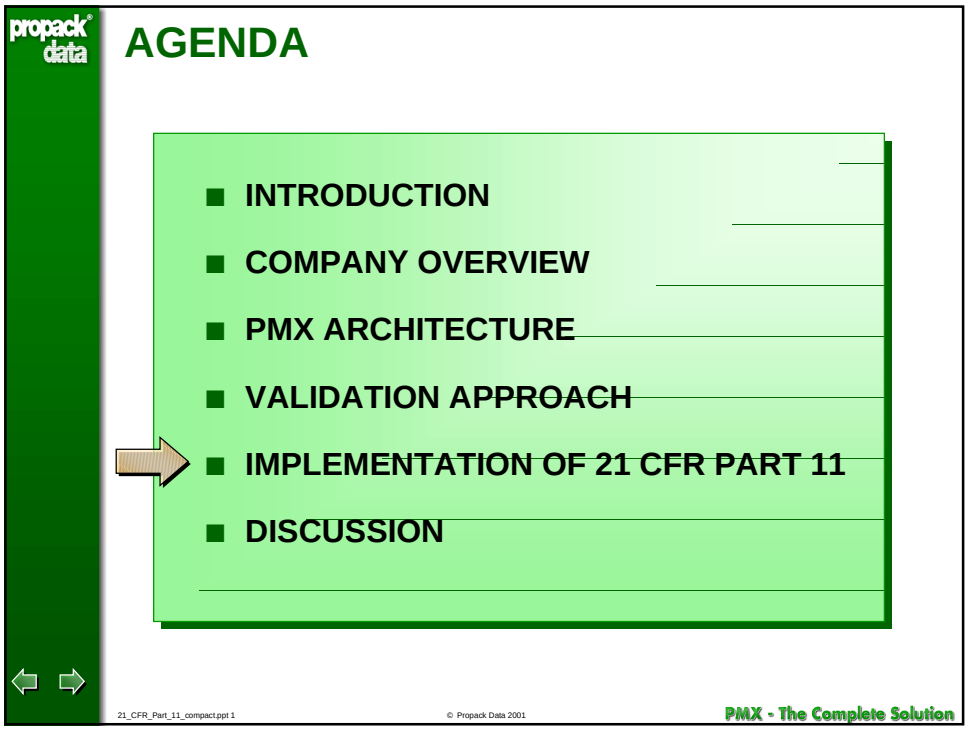
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AGENDA
INTRODUCTION
COMPANY OVERVIEW
PMX ARCHITECTURE
VALIDATION APPROACH
IMPLEMENTATION OF 21 CFR PART 11
DISCUSSION
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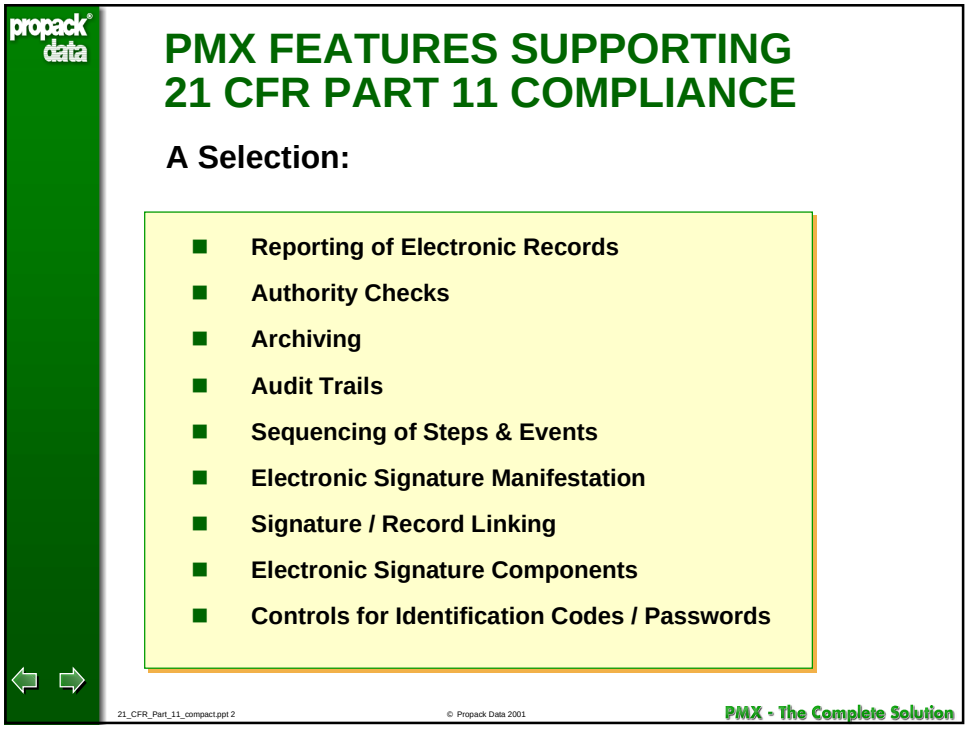
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PMX FEATURES SUPPORTING
21 CFR PART 11 COMPLIANCE
A Selection:
Reporting of Electronic Records
Authority Checks
Archiving
Audit Trails
Sequencing of Steps & Events
Electronic Signature Manifestation
Signature / Record Linking
Electronic Signature Components
Controls for Identification Codes / Passwords
21_CFR_Part_11_compact.ppt 2
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21 CFR PART 11 REQUIREMENTS

§11.10(b)

The system shall provide the ability to **generate accurate and complete copies of records** in both human readable and electronic form suitable for inspection, review, and copying by the agency.

Implementation in PMX

- **Reporting Features**

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21 CFR PART 11 REQUIREMENTS

§11.10(c)

The system shall ensure the **protection of records** to enable their accurate and ready retrieval throughout the records retention period.

§11.10(d)

Limiting system access to authorized individuals must be ensured.

Implementation in PMX

- **User Authorization**
- **Access Restrictions**
- **Archiving Features**

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21 CFR PART 11 REQUIREMENTS

§11.10(e)

The system must provide secure, computer-generated, time-stamped **audit trails** to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.

Implementation in PMX

- **Audit Trail**
- **Version Control**

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21 CFR PART 11 REQUIREMENTS

§11.10(f)

Use of operational system checks to **enforce permitted sequencing of steps and events**, as appropriate.

Implementation in PMX

- **Sequencing of Actions**

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21 CFR PART 11 REQUIREMENTS

§11.10(g)

Use of **authority checks** to ensure that only authorized individuals

- can use the system,
- electronically sign a record,
- access the operation or computer system input or output device,
- alter a record, or
- perform the operation at hand.

Implementation in PMX

- **User Authorization**
- **Certifying Authorization**
- **Access Restrictions**

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21 CFR PART 11 REQUIREMENTS

§11.50(a)

Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:
(1) The **printed name** of the signer;
(2) The **date and time** when the signature was executed; and
(3) The **meaning** (such as review, approval, responsibility, or authorship) associated with the signature.

Implementation in PMX

- **Signature Manifestation**

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21 CFR PART 11 REQUIREMENTS

§11.50(b)

Printed name of the signer, date and time, and meaning associated with the signature shall be subject to the **same controls as for electronic records and shall be included as part of any human readable form of the electronic record** (such as electronic display or printout).

Implementation in PMX

- **Management and Display of Electronic Signatures**

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21 CFR PART 11 REQUIREMENTS

§11.70

Signature/record linking:
Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that **the signatures cannot be excised, copied, or otherwise transferred** to falsify an electronic record by ordinary means.

Implementation in PMX

- **Signature / Record Linking**

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21 CFR PART 11 REQUIREMENTS

§11.200(a)(1)

Electronic signatures that are not based upon biometrics shall employ at least **two distinct identification components** such as an identification code and password.

Implementation in PMX

- **Signature Components**

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21 CFR PART 11 REQUIREMENTS

§11.300 (b)

The system shall provide controls ensuring that identification code and password issuances are **periodically checked, recalled, or revised** (e.g., to cover such events as password aging).

Implementation in PMX

- **Password Features**
- **Reporting for User Authorization**

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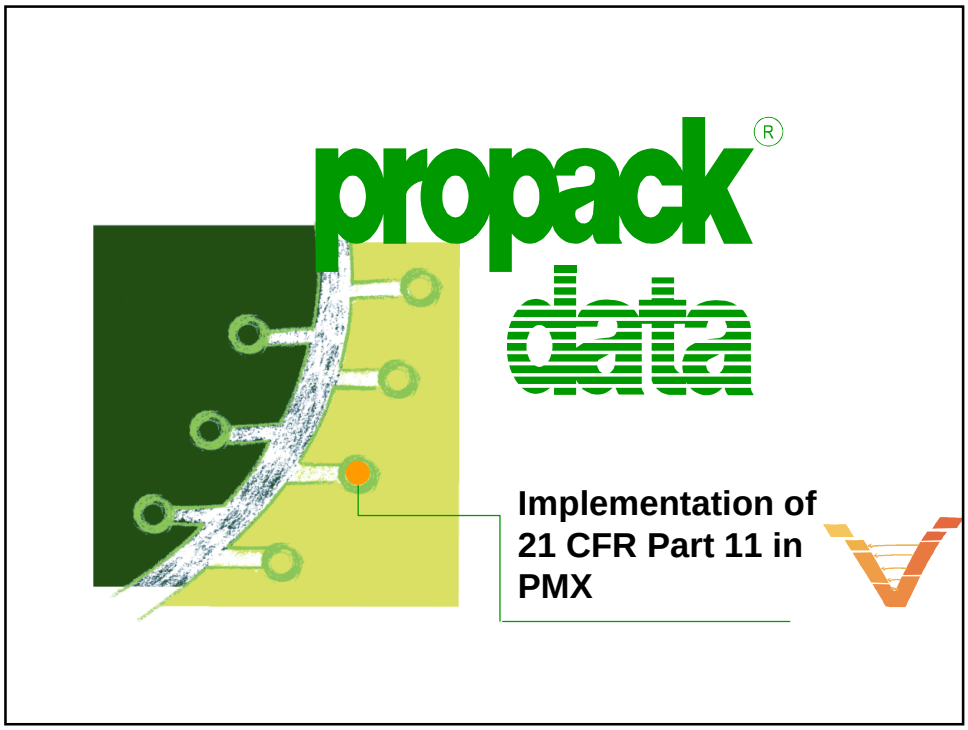
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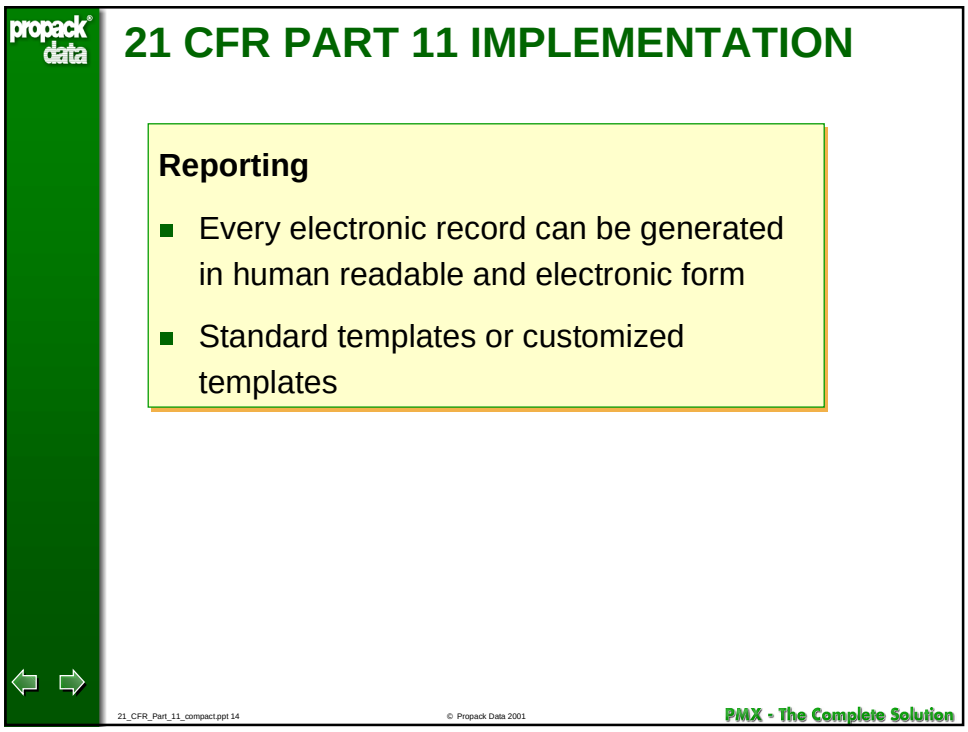
Implementation of
21 CFR Part 11 in
PMX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21 CFR PART 11 IMPLEMENTATION
Reporting
Every electronic record can be generated in human readable and electronic form
Standard templates or customized templates
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PMX - The Complete Solution

21 CFR PART 11 IMPLEMENTATION

Authorization

- Two kinds of Authorizations
  - Operational Authorization - *Execution*
    The rights required by an operator for **executing** a certain function
  - Certifying Authorization - *Approval*
    The rights required by a supervisor/operator for **certifying** that the results of a certain operation are in order
- Authorizations are associated with a Customer-specific Hierarchy of User Groups and Users

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21 CFR PART 11 IMPLEMENTATION

Access Restrictions

- Login Features
  - ✓ Configurable number of false Login Attempts
  - ✓ Protocol of all Login Attempts
- Password Features
  - ✓ Encrypted Storage
  - ✓ Configurable expiration
  - ✓ At least one Number or Special Character
  - ✓ At least 6 characters long
  - ✓ Restrictive “re-usability” of passwords
- Configurable Automatic Screen Lock mechanism during inactivity
- Database accessible only through controlled system functionality

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Audit Trail

- Comprises the Following:
  - A time-stamp
  - Field name
  - New value within the field
  - Old value within the field
  - The kind of transaction - (e.g. create, delete, modify)
  - Identification of the operator (login name)
  - An electronic signature, whenever appropriate
  - The reason for the change, whenever appropriate
- Generic Concept within PMX which can be configured for each Record Type separately - e.g. BOM, Production Procedure, …

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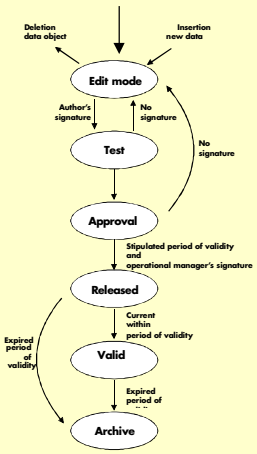
21 CFR PART 11 IMPLEMENTATION

Version Control

Work Flow Transition Graph of a Version Controlled Object

- **Represents workflow for data object**
- **State transition is coupled with specific authorization and electronic signature**
- **Automatic version numbering**
- **Old versions that have reached certain state are kept in archive**
- **System ensures that only *one* valid object at any *one* given time exists**
- **Setup of different approval flows for different objects by user**



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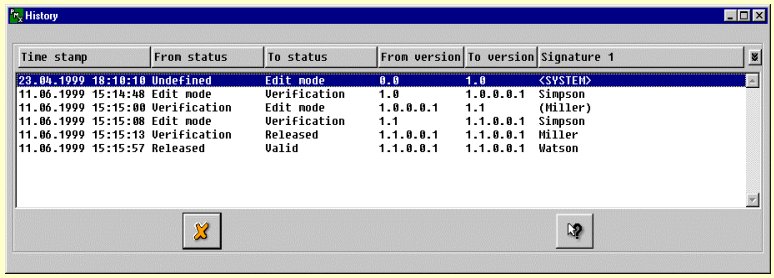
Version Control

Change History of a Data Object



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Sequencing of Actions

Sequencing enforced through basic system functions and configurable mechanisms, as e.g.

- User definable master batch record
- Version graphs defining workflow from editing to archiving
- Operation workflow for recipe-based weighing

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Management and Display of Electronic Signatures

- Signature components are displayed on every paper record/screen display as appropriate
- For practical reasons, signature information can be displayed on demand

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Mandatory

Signature Components

Requirement: Two distinct identification components

User Identification Code

Login Name
- **Unique**
- **Associated user rights**

Password

- **Secret**
- **protected by password features**

Please enter password:
******

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21 CFR PART 11 IMPLEMENTATION

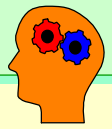
Recommendation

Signature Components

Requirement: Two distinct identification components

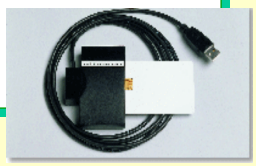
Logical Key

user identification code (ID-Code)
+ password
+ differentiated user management and rights system



Physical Key

e.g. Smartcard
with associated ID- code



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Signatures Manifestation in PMX

- Full name of signer stored within user profile and displayed in line of identification code
- Date and time always stored and displayed together with signature
- Meaning of Signatures
  - provided by context of signing, if appropriate (e.g. within a workflow)
  - provided by explicit declaration (e.g. within report)

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Signature / Record Linking

- Electronic Signatures are linked to Electronic Records (Data Objects) through Database Structure. DB Access is controlled through Database Management System.

Linking Handwritten Signatures

- Control of Printouts:
  Unique, successive numbering of copies

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Uniqueness of Signatures

- PMX refuses non-unique user Identification Codes
- User accounts that have been used cannot be deleted

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Protection from Fraud

System Features to prevent Fraud:

- Secure Password Features
- Access to Database only through System Functions
- System Administrator has no knowledge of Passwords

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21 CFR PART 11 IMPLEMENTATION

Password Features

- Encrypted Storage
- “Hidden” entry of password on screen
- Configurable Expiration
- At least one Number or Special Character
- At least 6 Characters long
- Restrictive “re-usability” of passwords

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Reporting for User Authorization

- Reporting functions for user / user group data available, displaying the rights of each user group and the correspondence of users to user groups

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Certifying Authorization - Implementation

- Can be bound to Transactions such as
  - Completion of an Operation step - Batch Recording, Monitoring, Weighing and Dispensing
  - Changing the Status of a Document under Version Control
  - Activation of Interaction Elements
- Certifying Rights are also Associated with either User Groups or Users

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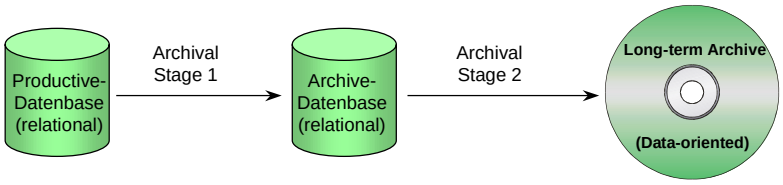
Archiving in PMX - Concepts



Archived Data	**Active data with all dependent Objects**	**Active data with all dependent Objects**
Time	**medium term, cyclic**	**long term, cyclic**
Data format / Storage Media	**1:1-image of the Structure in the Productive Database / Hard Disks**	**Standardized Data formats XML, HTML, PDF, .../ CD, DMS, ...**
Information content	**Complete Information content of Productive Database**	**compressed representation of the information**
Access Methods	**PMX**	**Data-Viewer DMS**

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